UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

PFIZER INC., PFIZER LIMITED and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs and Counterclaim Defendants, v. TEVA PHARMACEUTICALS USA, INC., Defendant and Counterclaim Plaintiff.	Civil Action No. 2:10-cv-00128-RBS-FBS

TEVA'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE AN AMENDED ANSWER AND COUNTERCLAIM

Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") submits this reply memorandum in support of its November 12, 2010 Motion for Leave to File an Amended Answer and Counterclaim ("Motion for Leave to Amend"; D.I. 55).

I. INTRODUCTION

A party seeking leave to amend its pleadings to add a defense and counterclaim of inequitable conduct must identify with particularity the "who, what, when, where, and how" of the inequitable conduct. Teva undoubtedly has done so – Teva's 47-paragraph narrative in its proposed amended pleading describes the alleged inequitable conduct in substantial detail. Indeed, Pfizer does not challenge Teva's identification of the what, when, where, and how of the inequitable conduct – Pfizer only questions the particularity of the "who." Pfizer tries to convert the range and depth of Teva's allegations into an argument that Teva identifies everyone

involved with the prosecution and reexamination of the '012 patent, but no one in particular. That argument should be rejected because Teva identifies four specific persons – Dr. Ellis (a named "inventor"), Gregg C. Benson and James T. Jones (Pfizer in-house patent counsel) and Gerard M. O'Rourke (outside patent counsel) – who it believes engaged in inequitable conduct before the United States Patent and Trademark Office ("PTO"), and describes in detail their knowledge of material information and their failure to disclose that information to the PTO during the prosecution and reexamination of the '012 patent.

Having surpassed the standard for pleading inequitable conduct with particularity, Teva's Motion for Leave to Amend should only be denied if the amendment would be prejudicial to Pfizer, Teva acted in bad faith or if the amendment would be futile. Pfizer does not allege prejudice or bad faith – Pfizer only argues that the amendment is futile on grounds that Teva's inference of deceptive intent is unreasonable. Pfizer's argument, however, is fatally flawed because Pfizer applies the wrong standard to the analysis. Pfizer suggests that for Teva's motion to be granted, Teva's inference of deceptive intent must be the *single most reasonable* inference able to be drawn from the evidence. That standard, however, is the burden that Teva must satisfy at trial to prove deceptive intent by clear and convincing evidence. We are not at trial. To prevail on its Motion for Leave to Amend to add a defense and counterclaim of inequitable conduct, Teva's inference of deceptive intent need only be reasonable. It must flow logically from the facts alleged.

Teva's proposed amended pleading meets and exceeds that standard because it alleges with particularity facts from which an inference of intent to deceive clearly flows. The aforementioned individuals engaged in numerous actions and inactions over the course of several years that each alone and cumulatively had the affect of keeping from the PTO material

information that would have cast doubt on the patentability of the claims of the '012 patent that are not limited to treating humans for erectile dysfunction ("ED") by orally administering a limited number of drug compounds. It is reasonable to infer that those highly-talented professionals did so with deceptive intent to broaden Pfizer's monopoly to include the treatment of humans with a far broader group of compounds and without limitation to a particular route of administration. That is all Teva needs to present in its amended pleading – it need not demonstrate that it is the only reasonable inference to be drawn. Indeed, it would be prejudicial to require Teva to do so without having substantial discovery.

The weakness of Pfizer's arguments for denying Teva's Motion for Leave to Amend is demonstrated by Pfizer's irrelevant polemic against the "plague" of allegations of inequitable conduct. Pfizer Opp. at 4-7.[1] The Federal Circuit decries "*unjustified* accusations of inequitable conduct" – not the legitimate, thoroughly investigated and particular pleading at issue here. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995). In *Molins*, on which Pfizer relied, the Federal Circuit found that an individual committed inequitable conduct, and stated that "[o]ne who has engaged in inequitable conduct has inflicted damage on the patent examining system … and on the public, which must face an unlawfully-granted patent. Loss of one's patent and damage to reputation are justified penalties for such conduct."[2] *Id*. Pfizer cannot deny that inequitable conduct is an accepted defense to a charge of patent infringement. The question whether inequitable conduct is asserted too much or too little in other cases is in any case

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[1] "Pfizer Opp. at __" refers to the corresponding page of Plaintiffs' Memorandum in Opposition to Teva's Motion for Leave to File an Amended Answer and Counterclaim.

[2] The quote by Judge Rader relied on by Pfizer is from a dissent in a 2008 case in which the Federal Circuit affirmed a District Court's finding of inequitable conduct. *Aventis Pharma SA v. Amphastar Pharms.* 525 F. 3d 1334 (Fed. Cir. 2008).

irrelevant here. As detailed in Teva's November 12, 2010 Memorandum in Support of its Motion for Leave to File an Amended Answer and Counterclaim, Teva conducted a painstaking review of voluminous documents to determine whether inequitable conduct occurred in this case. Only after Teva determined that it could plead inequitable conduct with the requisite particularity did it move for leave to file its proposed Amended Answer. Teva's allegations of inequitable conduct are particular and well justified.[3]

II. ARGUMENT

A. Teva's Amended Pleading Satisfies the Standard for Particularity Articulated in *Exergen*

The Federal Circuit's decision in *Exergen* requires a party pleading inequitable conduct as a defense or counterclaim to identify with particularity the "who, what, when, where, and how of the inequitable conduct." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). Pfizer's only argument about the particularity of Teva's proposed amended pleading is that it fails to adequately identify "who" acted with deceptive intent to deceive the PTO. Pfizer Opp. at 8-9. Pfizer is wrong and its argument is misleading.

Pfizer attempts to create the misimpression that Teva, like the accused infringer in *Exergen*, "alleges broadly that the Applicants acted with intent to deceive" (Pfizer Opp. at 8), and that "Teva's broad allegations of intent to deceive are not meaningfully different from the

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[3] Pfizer carelessly labels Teva "a prime offender, routinely alleging inequitable conduct." Pfizer Opp. at 7 n.6. Pfizer selectively identifies nine patent cases in which Teva alleged inequitable conduct over the past three years, but fails to point out that Teva is a party in 53 active patent cases in which Teva has not asserted inequitable conduct as a defense or counterclaim. Public records show that there are 71 currently active patent infringement actions in which Teva is a party – Teva has not alleged inequitable conduct in about 75% of those cases. Declaration of Keith A. Zullow in Support of Teva's Reply Memorandum in Support of Its Motion for Leave to File an Amended Answer and Counterclaim ("Zullow Decl.") at ¶ 2. Pfizer's selective identification of a handful of Teva cases and its casual suggestion that Teva reflexively asserts inequitable conduct in patent actions filed against the company is false and misleading.

allegation in *Exergen*, which was directed to 'Exergen, its agents and/or attorneys'" (Pfizer Opp. at 9). Pfizer acknowledges that Teva specifically identifies by name one of the two "inventors" of the '012 patent-in-suit, together with two particular in-house Pfizer patent lawyers and one particular outside patent lawyer as having engaged in inequitable conduct during the prosecution of the application for the '012 patent, but dismisses without explanation that very specific and particular pleading as "a perfunctory attempt to comply with Rule 9(b)…." *Id.* Teva respectfully submits that the Court should reject Pfizer's specious attempt to transform Teva's very careful, specific and particular proposed amended pleading into an extremely broad, non-specific pleading of the kind that the Federal Circuit found inadequate in *Exergen*.

As explained in its November 12, 2010 Memorandum in Support of Its Motion for Leave to File an Amended Answer and Counterclaim ("Teva Mem."), Teva, through an intensive and painstaking review of the voluminous public record of Pfizer's prosecution and reexamination of the '012 patent, and a careful review of a number of documents produced by Pfizer, has identified four particular individuals who engaged in inequitable conduct in one or both of those proceedings and their respective roles in those proceedings. Teva Mem. at Section II.B. Teva's proposed Amended Answer and Counterclaim particularly identifies the following four persons as having acted with intent to deceive the PTO during the prosecution of the application for the '012 patent: Dr. Peter Ellis, one of the two named "inventors"; Pfizer in-house prosecuting attorneys Gregg C. Benson, Esq., and James T. Jones, Esq.; and an outside prosecuting attorney, Gerard M. O'Rourke, Esq. *See, e.g.*, Proposed Amended Answer and Counterclaim at ¶¶ 43, 45 and 47.[4] Teva's proposed pleading also specifically identifies three of those particular

[4] Teva's proposed Amended Answer and Counterclaim is attached as Exhibit A to Teva's Motion for Leave to Amend.

individuals as having acted with intent to deceive the PTO during the reexamination of the '012 patent: Dr. Ellis and attorneys Benson and Jones. *Id*. at ¶ 60.[5]

Pfizer repeatedly asserts that Teva "accuses everyone involved in prosecuting the '012 patent with inequitable conduct" (Pfizer Opp. at 8), that Teva has made "blanket allegations of serious intentional misconduct on the part of … all of the attorneys who participated in the prosecution of the '012 patent…." (*id.* at 1), and that "Teva alleges that everyone who had a hand in the prosecution of the '012 patent intended to deceive the PTO" (*id*. at 2). Nothing could be further from the truth. Based on the original Power of Attorney that the named inventors filed during the prosecution of the '012 patent, Pfizer's Initial Disclosure and Pfizer's responses to interrogatories, at least 35 people were involved in the prosecution of the application for the '012 patent. *See* Zullow Decl. Ex. 24, Power of Attorney; Ex. 25, Pfizer's Initial Disclosure; and Ex. 26, Pfizer's Interrogatory Response. Teva, however, alleges only that four of those individuals engaged in inequitable conduct, and Teva has done so very cautiously. Teva identifies "inventor" Ellis as having engaged in inequitable conduct, but does not accuse the other "inventor," Dr. Nicholas Terret, of any misconduct. Teva accuses only one of the many outside attorneys (Mr. O'Rourke) and only two (Messrs. Benson and Jones) of the 28 Pfizer representatives identified in the Power of Attorney of engaging in inequitable conduct in connection with the prosecution of the '012 patent. *See* Zullow Decl. Ex. 24, Power of Attorney.

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[5] Document production in this case is ongoing; depositions have not yet been taken. Because substantial discovery remains to be taken, Teva's proposed amended pleading acknowledges that the evidence might show that others associated with the prosecution and reexamination of the '012 patent also may have engaged in inequitable conduct before the PTO. *See, e.g.*, Proposed Amended Answer and Counterclaim at ¶¶ 47, 60. That acknowledgement, however, does not convert Teva's careful and particular pleading into a general non-particular pleading like the pleading that the Federal Circuit rejected in *Exergen*.

The very particular allegations in Teva's proposed amended pleading are not remotely like the general allegations of inequitable conduct that the Federal Circuit deemed insufficient in *Exergen*. The *Exergen* pleading included seven paragraphs generally alleging that Exergen, a corporation, failed to identify two patents to the PTO that Exergen previously learned of during the prosecution of earlier-filed patent applications. *Exergen*, 575 F.3d at 1329-30. The defendant in *Exergen* did not attribute the alleged inequitable conduct to any particular individual. In contrast, Teva's 47-paragraph narrative describing the alleged inequitable conduct identifies four persons who Teva believes engaged in inequitable conduct before the PTO (Proposed Amended Answer and Counterclaim at ¶¶ 43, 45, 47 and 60), and describes in detail their knowledge of material information and their failure to disclose that information to the PTO during the prosecution and reexamination of the '012 patent (*id*. at ¶¶ 30-47, 50-60). Unlike the plaintiff in *Exergen,* Pfizer has fair notice of the identity of the particular individuals who Teva believes engaged in inequitable conduct and the facts underlying Teva's inequitable conduct allegations. No more is required of Teva's pleading under the law. *WesternGeco v. Ion Geophysical Corp.*, No. 09-cv-1827, 2009 WL 3497123, at *7 (S.D. Tex. Oct. 28, 2009) ("The heightened pleading requirements of Rule 9(b) do not require that WesternGeco definitively prove the merits of its claim. What is determinative here is that Ion was given fair notice of the basis for WesternGeco's inequitable conduct defense.").[6]

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[6] At least one District Court has found that *Exergen's* "who" requirement is more easily met if the inequitable conduct allegations are made early in the discovery process. *Mitsubishi Heavy Indus., Ltd. v. General Co.*, No. 5:10 CV 05087, 2010 WL 3328329, at *4, 5 (W.D.Ark. Aug. 23, 2010) ("In *Exergen*, the defendant had had an opportunity to conduct discovery before moving to amend the complaint to add the affirmative defense of inequitable conduct … Here, Mitsubishi has not had an opportunity to conduct discovery … True, the complaint does not name the specific individuals within GE who were responsible for the alleged fraud, but for the reasons stated in *Abels*, that is not required at

B. Teva's Inference of Deceptive Intent Is Reasonable – That Is All That Is Required at the Pleading Stage

Pfizer argues that "[Teva's] inference of deceptive intent 'must be "the *single most reasonable* inference able to be drawn from the evidence"'" (Pfizer Opp. at 9 n.9) and asserts that Teva's inferences of Pfizer's intent to deceive the PTO "are manifestly unreasonable" (Pfizer Opp. at 1). Both of Pfizer's arguments are wrong. Pfizer's suggestion that Teva's inference of deceptive intent must be the single most reasonable inference to be drawn confuses the burden that Teva must satisfy at trial to prove deceptive intent by clear and convincing evidence with the standard that Teva must satisfy now in its Motion for Leave to Amend its pleading. To prevail on a Motion for Leave to Amend a pleading to add a claim or defense of inequitable conduct, Teva's inference of deceptive intent need only be reasonable – it must flow logically from the facts alleged. *Exergen*, 575 F.3d at 1329 n.5. ("A reasonable inference is one that is plausible and that flows logically from the facts alleged."). Teva's proposed amended pleading meets and exceeds that standard because it alleges with particularity facts from which an inference of intent to deceive clearly flows.

In a moment of candor, Pfizer acknowledges that an inference of deceptive intent satisfies Rule 9(b) if it "is plausible and … flows logically from the facts alleged.…" Pfizer Opp. at 9. Pfizer, however, mischaracterizes Teva's proposed amended pleading by arguing that "inferring from the facts alleged by Teva that everyone involved in the prosecution of the '012 patent acted with intent to deceive the PTO is not reasonable." Pfizer Opp. at 9. Teva, of course, is not asserting that "everyone involved in the prosecution of the '012 patent" acted with intent to

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this stage. The degree of specificity that GE demands cannot reasonably be required absent discovery.") Here, where Teva has yet to take a single deposition, it would be unreasonable to require more than the very specific and particular allegations that Teva has asserted on the basis of an extensive and careful review of the publicly-available documents and Pfizer production documents currently available to Teva and its counsel.

deceive the PTO. Teva's inferences of intent relate directly to the four specific individuals identified in Teva's proposed amended pleading (*see supra*, Section II.A.), and flow logically from the facts alleged therein as explained below. That is all that is required for Teva to prevail on its Motion for Leave to Amend. *Exergen*, 575 F.3d at 1329 n.5.

Because it cannot fairly contend that Teva's pleading fails to satisfy the pleading requirements of Rule 9(b), Pfizer instead resorts to attacking the sufficiency of Teva's proof of deceptive intent on the merits rather than the adequacy of the pleading. *See* Pfizer Opp. at 10-13. A challenge directed to the merits of a defense or counterclaim at this point in the case cannot defeat a motion for leave to amend Teva's pleading to allow Teva to assert an inequitable conduct defense. *Nycomed U.S. Inc. v. Glenmark Generics Ltd.,* No. 08-cv-5023, 2010 WL 1257803, at *17 (E.D.N.Y. Mar. 26, 2010) (granting Rule 15(a) motion because opposing party challenging sufficiency of proof of scienter "attack[s] the merits of [movant's] inequitable conduct claim, not whether the claim has been adequately pled," and reviewing several post-*Exergen* cases reaching similar result); *see also HTC Corp. v. IPCom GmbH & Co., KG*, 671 F.Supp.2d 146, 151 (D.D.C. 2009) (patentee's arguments "that the prior art references are lengthy and [the alleged infringer] has not proven that the named inventors read the [relevant] pages … confuse the burdens of proof at trial with the pleading requirements of Rule 9(b)"). Pfizer's assertion that Teva's inferences of deceptive intent are "manifestly unreasonable" is wrong in any event, and Teva respectfully submits that the Court should reject Pfizer's attack on the merits for the additional reasons explained below.

1. The Facts Support an Inference that Pfizer Wants to Maintain Its Broad Animal Claims

Pfizer ridicules as "wholly implausible" Teva's inference that Dr. Ellis and attorneys Benson, Jones and O'Rourke engaged in inequitable conduct to preserve the claims of the '012

patent directed to treatment of ED in male animals in the '012 patent, and asserts the broad monopoly alleged by Teva is "meaningless". Pfizer Opp. at 10-11. Pfizer's argument should be rejected because it fundamentally mischaracterizes Teva's argument about the scope of the patent claims directed to animals, and because it is inconsistent with Pfizer's actions in this case and in the past.

Claims 1, 3-19 and 21-23 of the '012 patent cover the administration of the compounds described in those claims to animals, ***including humans***. They are ***not*** limited to non-human animals. Many of those claims are potentially useful to Pfizer because they cover methods of preventing ED in humans that are far broader than the human-only claims in the '012 patent. The human-only claims of the '012 patent all are limited to oral administration of the claimed compounds. Whitehill Decl. Ex. 1,[7] '012 patent Claims 20, 25 and 26. In contrast, many of the animal claims, which also cover humans, do not limit the manner in which they can be administered, and therefore cover other forms of administration, such as intravenous, sublingual or buccal administration. *Id*. at Claims 5, 21, 22. Pfizer, separate and apart from the fact that those claims also cover animals other than humans, has an incentive to preserve those animal claims so that it can prevent others from using sildenafil and many PDE5 inhibitor compounds, other than sildenafil, to prevent ED in humans using methods in which those compounds are administered orally or non-orally.

Teva's proposed amended pleading recognizes the broad scope of the monopoly secured by those animal claims, alleging that "at least Dr. Ellis and Messrs. Benson, Jones and O'Rourke acted with deceptive intent to secure broad claims directed to the use of sildenafil to treat erectile

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[7] "Whitehill Decl. Ex. ___" refers to the corresponding Exhibit to the November 12, 2010 Declaration of Joshua A. Whitehill in Support of Teva's Memorandum in Support of its Motion for Leave to File an Amended Answer and Counterclaim (D.I. 57).

dysfunction in any animal." Proposed Amended Answer and Counterclaim at ¶ 47; *see also id.* at ¶ 60. Contrary to Pfizer's mischaracterization, Teva did not limit its allegations merely to an inference that Pfizer wanted to preserve those claims only for purposes of preventing others from treating non-human animals. Indeed, Claim 2 of the '012 patent is the ***only*** claim that encompasses animals without also covering humans. Teva's allegation is that Dr. Ellis and Messrs. Benson, Jones and O'Rourke sought to obtain and maintain broad claims that cover both animals and humans, claims that provide coverage broader than that of the human-only claims in terms of the subjects to be treated (human ***and*** non-human animals), the compounds used in the methods to prevent ED (many PDE5 inhibitors, not just sildenafil), and the routes of administration (oral ***and*** non-oral). Pfizer also had and has an incentive to obtain and maintain the unasserted animal claims that cover human and non-human animals so that Pfizer can use those claims against other potential defendants if the human-only claims are invalidated.

Pfizer ignores all of that and argues that "the 'broad monopoly' urged by Teva was meaningless" because there is no market for using sildenafil to treat non-human animals and because Pfizer never sought to develop Viagra® for treating non-human animals. Pfizer Opp. at 10-11. Pfizer states that if it believed maintaining the animal claims would put the human-only claims at risk, Pfizer would have "dropped" the '012 patent animal claims as it did in the Canadian patent. Pfizer Opp. at 11. That argument is erroneous because unlike in Canada, partial disclaimer of claims is not permitted under the patent laws of the United States. *See* 37 C.F.R. § 1.321(a) ("A patentee owning the whole or any sectional interest in a patent may disclaim any ***complete*** claim or claims in a patent." (emphasis added)). Thus, Pfizer would have had to disclaim all of the claims in the '012 patent other than Claims 25 and 26 (which are the only claims that Pfizer has asserted against Teva). Doing so would have eliminated Pfizer's

patent protection for non-human animals, Pfizer's patent protection for the millions of compounds other than sildenafil that are encompassed by the "animal" claims but are not covered by the human-only claims (*see, e.g*., Claim 1), and Pfizer's monopoly on non-oral routes of administration.[8] For all of those reasons, Pfizer had a strong incentive to maintain the broad animal claims.

Pfizer's assertions that its non-human animal claims lack value is inconsistent with Pfizer's actions in this case and in the past. On numerous occasions in this action, Teva asked Pfizer for a covenant not to sue with respect to unasserted Claims 1-23 of the '012 patent. Zullow Decl. Ex. 27, Aug. 2010 Letter at 5; Ex. 28, Oct. 2010 Letter at 3. Pfizer has not given Teva the requested covenant not to sue. If, as Pfizer now contends, the non-asserted animal claims are meaningless, it seems clear that Pfizer should be willing to give Teva a covenant not to sue on those claims. Other actions by Pfizer are inconsistent with its litigation-inspired argument that the animal claims are worthless. Pfizer's first sildenafil patent, which also was prosecuted by attorneys Benson and Jones, is directed to, *inter alia*, the use of sildenafil to treat hypertension. Zullow Decl. Ex. 29, '534 patent. The method claim in that patent is limited to the use of the claimed compounds in humans. *Id* at Claim 8. In the later prosecuted '012 patent, however, Messrs. Benson and Jones disclosed and claimed the treatment of non-human animals as well as humans. *See, e.g.,* Whitehill Decl. Ex. 1, '012 patent at 6:4-27 and Claims 1-19 and 21-23. Indeed, of the 26 claims originally allowed in the '012 patent, 23 covered the administration of the claimed compounds to animals. It is hard to believe that Pfizer and its prosecuting attorneys Benson and Jones would specifically file and prosecute a host of animal

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[8] Pfizer could have sought to reissue the '012 patent with narrower human-only claims, but doing so would have re-opened prosecution of the patent with a concomitant risk of rejection of the human-only claims. 37 C.F.R. § 1.176(a) ("A reissue application will be examined in the same manner as a non-reissue, non-provisional application.").

claims in the '012 patent without a belief that they had value. The logical inference is that Pfizer has and still does value the animal claims of the '012 patent. That is why Pfizer chose to withhold material information from the PTO, still is trying to preserve its broad animal claims and is not willing to give Teva a covenant not to sue on those claims.[9]

2. There is No Material Difference Between the Canadian and U.S. Claims Directed to Animals

Pfizer contends that Teva's reliance on Dr. Ellis' sworn statements from the litigation involving Pfizer's Canadian counterpart patent is misplaced on grounds that the animal claims in the '012 patent and in Pfizer's Canadian counterpart of the '012 patent, CA 2,163,446 ("the '446 patent") are materially different. Pfizer Opp. at 10. The sole basis for Pfizer's argument is that the animal claims in the '012 patent include the phrase "in need of such treatment," while the animal claims in the '446 patent do not. The animal claims of the '012 patent, however, suffer the same overbreadth problem that led Pfizer to disclaim the counterpart claims in Canada, notwithstanding the inclusion of the language "in need of such treatment" in the claims of the '012 patent. Dr. Ellis and Messrs. Jones, Benson and O'Rourke had an obligation to alert the PTO about that overbreadth. Their failure to do so constitutes inequitable conduct.

The '446 patent originally issued with many claims directed to the use of sildenafil to treat ED in animals. Whitehill Decl. Ex. 2, '446 patent, Claims 1–7, 10–13, 16, 17 and 20–24.

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[9] Even if the animal claims of the '012 patent are meaningless, courts have held that is no basis for denying Teva's Motion for Leave to Amend because "[p]eople are dishonest and break the law even when small amounts of money are at stake." *Nilssen v. Osram Sylvania, Inc.*, 440 F.Supp.2d 884, 905 (N.D. Ill. 2006) ("Nilssen's argument that he would not have intentionally paid small entity fees because the amount of money he was saving was too small relative to what he might lose if his patents were declared unenforceable is without merit.") (citing *Daimlerchrysler AG v. Feuling Advanced Techs., Inc.*, 276 F.Supp.2d 1054, 1062 (S.D. Cal. 2003) ("Why [patentee] and his agents would put the enforceability of patents licensed for millions of dollars at risk to save a few thousand dollars in PTO fees is beyond reason. Yet, the evidence overwhelmingly supports the inference that they did so, and common experience confirms that the world has no shortage of individuals who commit irrational and self-destructive acts.").

Dr. Ellis, one of the named inventors of the '446 patent, told a Canadian court that Pfizer disclaimed the non-human animal subject matter in those claims because the claim term "animal" in the '446 patent was "much too broad" and was "a mistake." Whitehill Decl. Ex. 3, Ellis Aff. at ¶¶ 59, 60.

The animal claims in the '012 patent likewise claim a method of treating ED in animals, but they also include language that the animal is "in need of such treatment" – a phrase that did not appear in the Canadian animal claims. Pfizer argues that those words limit the animal claims in the '012 patent to treatment of animals with penises, rendering the animal claims of the '012 patent more narrow than and materially different from the claims in Canada. Teva respectfully submits that the Court should reject that specious argument because the '446 patent in Canada (like the '012 patent) expressly defines ED in a way that limits the claims to the treatment of animals with penises, without regard to whether the claim includes the additional phrase "in need of such treatment." Both patents define ED as "an inability to obtain or sustain an erection adequate for intercourse." Whitehill Decl. Ex. 2, '446 patent, at 1; Ex. 1, '012 patent at 1:12-14. That definition necessarily contemplates a penis – only animals with a penis can have an inability to obtain or sustain an erection adequate for intercourse. The language in the '012 patent upon which Pfizer relies does not render the animal claims of the '012 patent materially different in terms of the scope of the species covered from the animal claims of the '446 patent, nor does it remedy the overbreadth that led Pfizer to disclaim the non-human animal subject matter in the claims of the '446 patent.

The definition of ED in the '446 patent necessarily limited the animal claims in that patent to the treatment of animals with penises. Dr. Ellis nevertheless told a Canadian court that those claims were "much too broad" and "a mistake." According to Dr. Ellis, it was reasonable

to predict that the claimed compounds would be effective to treat ED in animals with penises similar in operation to that of humans. Whitehill Decl. Ex. 3, Ellis Aff. at ¶ 59. As Pfizer admits, "Dr. Ellis deemed the word 'animals' too broad, though, in that it included 'mammals' as well as 'birds, reptiles and insects.'" Pfizer Opp. at 10. Each of those four animal kingdoms includes species with penises,[10] but Dr. Ellis did not know whether the penises of all of those species were similar in operation to that of humans, so that one could reasonably predict that the claimed compounds would treat ED in all of those species. The animal claims of the '446 patent, therefore, were "much too broad," leading to Pfizer's disclaimer. The animal claims of the '012 patent do not materially differ in scope of the species covered from those of the '446 patent and therefore suffer from the same overbreadth as the claims Pfizer disclaimed in Canada.

3. Pfizer Could and Should Have Disclosed the Bayer Allegations to the Patent Office Before the '012 Patent Issued

Pfizer does not deny that Dr. Ellis and Messrs. Benson, Jones and O'Rourke knew about Bayer's Canadian allegations of overbreadth before the '012 patent issued.[11] Pfizer also does not deny that there were mechanisms that Pfizer could have employed to bring the Bayer allegations to the attention of the PTO before the '012 patent issued. Instead, Pfizer claims that by the time Messrs. Benson, Jones and O'Rourke "could have become aware" of the allegations, the PTO

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[10] At least some species of birds, reptiles and insects have penises. Zullow Decl. Ex. 30, Höhn at 547 ("[i]n adult wild mallards the penis weighs about 0.6 gms"); Ex. 31, Khanna *et al*. at 16-17 (in reptiles such as "crocodiles and tortoises there is a single median penis"); Ex. 32, Snodgrass at 5 (in the Thysanura, a class of insect, "the penis lies between a pair of stylus-bearing plates").

[11] Pfizer's arguments about the bovine retractor penis are another improper attempt to argue the sufficiency of Teva's evidence in support of its inequitable conduct claim rather than making germane arguments about whether Teva has adequately pled its claim. Pfizer does not deny that Dr. Ellis and Messrs. Jones, Benson and O'Rourke knew about Bayer's Canadian allegations of overbreadth before the '012 patent issued, or that Dr. Ellis knew, before the issuance of the '012 patent, that certain animals have penises that do not function in the same manner as human penises. Details about bovine retractor penis functions are not relevant now.

already had allowed the claims and "closed the '012 patent prosecution," and that because Pfizer had paid the issue fee, Pfizer could no longer submit the Bayer allegations to the PTO in an Information Disclosure Statement ("IDS"). Pfizer Opp. at 11-12. That argument is misleading and should be rejected – although Pfizer could not submit an IDS after the issue fee was paid, the duty of candor continues until the patent issues, and Pfizer certainly could and should have withdrawn the application from issuance to allow Dr. Ellis and Messrs. Jones, Benson and O'Rourke to satisfy their duty of candor by giving the PTO an opportunity to consider the Bayer allegations:

> The duty to disclose information, however, does not end when an application becomes allowed but extends until a patent is granted on that application. The rules provide for information being considered after a notice of allowance is mailed and before the issue fee is paid. ***The rules also provide for an application to be withdrawn from issue*** (A) because one or more claims are unpatentable; [or] (B) for express abandonment so that information may be considered in a continuing application before a patent issues …

Zullow Decl. Ex. 33, MPEP § 2001.04 (emphasis added; internal citations omitted).[12] Pfizer had a duty to withdraw the application for the '012 patent from issue to allow the PTO to consider the Bayer allegations, but it failed to do so.

Pfizer also misleadingly asserts that "Pfizer provided the PTO with the Bayer Statement of Claim and the Canadian disclaimer at the first opportunity" and suggests that cured its failure to do so during the prosecution of the '012 patent. Pfizer Opp. at 12. As explained above, Pfizer could have disclosed the Bayer allegations to the PTO before the '012 patent issued and had an

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[12] "[A]lthough [the MPEP] does not have the force of law, [it] is well known to those registered to practice in the PTO and reflects the presumptions under which the PTO operates." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d. 1253, 1257 (Fed. Cir. 1997). The MPEP "is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith." *Molins*, 48 F.3d at 1180 n.10.

affirmative duty to do so. Furthermore, the law is clear that Pfizer's disclosure of the Bayer allegations during the later reexamination of the '012 patent does not cure the inequitable conduct committed during prosecution of the '012 patent. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1241 (Fed. Cir. 2003) (disclosure during reissue proceeding "irrelevant" to whether the patentee committed inequitable conduct in acquiring the patent, an inquiry that centers on the patentee's "intent during the prosecution of the original application"); *Molins*, 48 F.3d at 1182 ("We recognize that [the withheld references] were cited eventually to the PTO and that the examiner initialed them and passed the reexamination application to issue thereafter. However, the references were not cited when they should have been.").

Pfizer incorrectly asserts that Teva's inference of deceptive intent regarding Pfizer's submission of the Ellis affidavit to the PTO five years after its creation is unreasonable "given that Pfizer provided the PTO with the Bayer Statement of Claim and the Canadian disclaimer at the first opportunity and given that the 'animal' claims were of no commercial significance." Pfizer Opp. at 12. Pfizer's conclusion is wrong because it is premised on faulty predicates: Pfizer plainly did not provide the PTO with the Bayer allegations at the first opportunity, and Pfizer's actions contradict Pfizer's current assertion that the "animal" claims were of no commercial significance (*see supra*, Section II.B.1.).

The manner in which Pfizer submitted the Bayer allegations and the Canadian disclaimer to the PTO support Teva's inference of deceptive intent. Dr. Ellis and Messrs. Benson, Jones and O'Rourke had a duty to withdraw the '012 patent from issue to give the PTO an opportunity to consider the Bayer allegations. If they had done so, the Bayer allegations would have been brought directly to the PTO Examiner's attention. Instead, Pfizer let the '012 patent issue and later tried to bury the Bayer allegations (and the Canadian Disclaimer) in nine boxes of

documents containing over 680 references that Pfizer dumped on the PTO in a single IDS. Zullow Decl. Ex. 34, Nov. 25, 2003 IDS. The MPEP specifically advises applicants submitting a long list of documents, as Pfizer did, to "[e]liminate clearly irrelevant and marginally pertinent cumulative information … [and] highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance." Zullow Decl. Ex. 35, MPEP § 2004. Pfizer ignored that direction, choosing to bury rather than "highlight" the Bayer allegations and the Canadian Disclaimer.

The Ellis Affidavit, which was the first document to fully explain the relevance of the Bayer allegations and the Canadian Disclaimer, was withheld by Pfizer from the PTO without explanation for five years after its creation and until after the PTO indicated in the reexamination that all of the claims, except Claim 24, in the '012 patent were allowable. Pfizer does not explain why it waited so long to submit the Ellis Affidavit to the PTO, or why it failed to highlight it for the PTO during the reexamination of the '012 patent. All of those facts support the reasonableness of Teva's inference of deceptive intent.

Pfizer asserts in a footnote that it withheld the highly material Apotex Memoranda from the PTO because they were cumulative of the Bayer allegations and Canadian Disclaimer. Pfizer Opp. at 13 n.14. Pfizer's argument should be rejected. The Apotex Memoranda equate the overbreadth of the Canadian claims with the animal claims in the '012 patent:

> Although Pfizer alleges that the first disclaimer (December 2002) corrects various mistakes, it is curious that the corresponding U.S. patent, U.S. 6,469,012, which issued October 22, 2002, claims the treatment of ED in a male animal, the same "mistake" corrected in the '446 Patent, which issued four years earlier."

Whitehill Decl. Ex. 21, 05/11/07 Apotex Memorandum at ¶ 108; *see also* Ex. 22, 04/08/08 Apotex Memorandum at ¶ 104. The Apotex Memoranda are not cumulative because none of the other documents that Pfizer ultimately submitted to the PTO make that connection. Pfizer's

failure to disclose the Apotex Memoranda to the PTO further supports Teva's inference of deceptive intent.

III. CONCLUSION

For all of the foregoing reasons, Teva respectfully asks the Court to grant Teva's Motion for Leave to File an Amended Answer and Counterclaim.

Dated: December 6, 2010

By: /s/

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CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of December, 2010, I will electronically file the foregoing Teva's Reply Memorandum in Support of Its Motion for Leave to File an Amended Answer and Counterclaim with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing to the following counsel of record:

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